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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,201	03/31/2006	Hiroynki Sugawara	1034509-000002	8956
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EXAMINER MARCEYICH, ADAM M				
ART UNIT		PAPER NUMBER		
3761				
NOTIFICATION DATE		DELIVERY MODE		
09/18/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary

Application No.

10/574,201

Applicant(s)

SUGAWARA, HIROYUKI

Examiner

Adam Marcetich

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 4, 7-13, 15, 16, 20 and 26-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3, 4 and 7-13 is/are allowed.
- 6) ☒ Claim(s) 20 is/are rejected.
- 7) ☒ Claim(s) 15, 16 and 26-30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 June 2008 has been entered.

Priority

2. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of Japan 2003-344752, filed on 02 October 2003 has been filed.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 15, 16, 20, and 26-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 20 recites the language "a filter unit to be aseptically connected to a connected bag set" and later, "... wherein either said first tube or said third tube is

aseptically connected to said second tube by using an apparatus for aseptically connecting tubes . . .” A question exists whether the claim is directed to a filter connected to a tubing loop (second tube) as set forth in FIGS 1, 3, 4, and 6, or whether the filter is connected to a bag set (third tube) as illustrated in FIGS 2, 5, and 7. To clarify, this set of claims is directed to a device and not a method of assembling. In other words, a filter connected to a tubing loop with *both* ends connected to the filter inlet and outlet versus a filter connected to a bag set with multiple tubing ends are two mutually exclusive devices, and cannot appear in the same claim. Therefore, the claim should be amended to specifically point out whether the filter is connected to a loop or connected to a connected bag set is being claimed.

6. Examiner suggests amending claim 20 as a product-by-process claim, to particularly point out and distinctly claim whether the filter unit is connected to a loop or connected bag set. Examiner notes that Product by Process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Therefore, a burden exists for the Applicant to show an unobvious difference between the structures of the claimed device and prior art. In other words, a device (in this case the filter connected to a bag set) produced by the claimed process (the filter originally connected to a second tube as a loop, later connected to a bag set through aseptic coupling) requires structural characteristics differentiating it from the prior art (a filter already connected to a bag set). See MPEP 2113.
7. The deficiencies of claim 20 are imputed to its dependent claims 15, 16, 20, and 26-30.

ALLOWABLE CLAIMS

8. Claims 3, 4 and 7-13 are allowed over the prior art of record.
9. Although no art rejections have been applied to claim 20 and its dependents, this does not constitute an indication of allowability of the claims. Generally, the Examiner cannot predict how Applicant will amend claims to remedy a 112 error and therefore, since the claims are unclear, one cannot reasonably apply art. Examiner recommends amending claim 20 and its dependents considering prior art made of record and disclosure in the immediate specification.

REASONS FOR ALLOWANCE

10. The following is an Examiner's statement of reasons for allowance:
11. The closest prior art of record, Johnson et al. (US Patent 5,180,504), discloses the limitations of:
- a primary bag (column 4, lines 13-24 and Fig. 6, primary bag 16);
 - a secondary bag (column 7, lines 15-22 and Fig. 6, transfer bag 34);
 - a filter unit comprising an inlet and an outlet (Fig. 6, filtration device 40 having upper and lower ends); and
- tubing made from PVC (column 4, lines 42-46), a plastic capable of being cut, melted and aseptically connected. However, Johnson fails to teach or fairly suggest alone or in combination the essential steps of the claimed method and device, such as cutting a second tube, both ends of which are connected to said inlet and said outlet,

and to which a bag is not connected. This limitation appears in claims 3 and 4 of the amended claims filed 25 June 2008. Additionally, Johnson lacks a step of cutting a second tube (attached to the filter) so that the second tube comprises first and second cut ends. This step is critical since it allows a filter unit 14 to be sterilized using a different method than applied to a connected bag set 1 (specification p. 22, lines 12-21). Additionally, this configuration of a second tube in a closed cyclic circuit allows the inside of a filter to remain sterile without additional packaging, thus reducing costs.

This step of cutting a "second tube, both ends of which are connected to said inlet and said outlet, and to which a bag is not connected" is supported in the immediate specification (p. 20, lines 15-19; p. 21-22, lines 22-2 and Figs. 1, 2, tubes 5 and 16 connected at marks A1, A2, B1 and B2).

12. Similarly, Fell (US Patent 6,733,433) discloses the limitations of:

a primary bag (col. 6, lines 60-66, Fig. 3, bag 40);

a plurality of secondary bags (column 6, lines 66-67 through column 7, lines 1-2, column 8, lines 59-63 and Fig. 3, bags 42-44 respectively); and

a filter (column 6, lines 60-66 and Fig. 3, bacterial filter 54). However, Fell lacks the critical step of cutting a second tube attached to a filter as claimed [claims 3 and 4]. Additionally, bacterial filter 54 as taught by Fell is not disclosed as performing leukoreduction or leukofiltration.

13. Also important to note, Kuroda et al. (US Patent 4,985,153) discloses the limitations of:

a primary bag and a plurality of secondary bags (col. 3, lines 38-47, Fig. 2, blood collector means 1 and satellite bags 4 and 5);

a filter (col. 3, lines 38-42, Fig. 1, Figs. 1-2, filter means 2); and

cutting a conduit connecting bags (col. 4, lines 34-41). Kuroda further discloses tubing made of PVC, which is adaptable for sterile cutting and hermetic sealing (col. 15, lines 49-61). However, Kuroda lacks the critical step of cutting a second tube attached to a filter as claimed [claims 3 and 4]. Additionally, Kuroda discloses the system as being sterilized in a single step, which teaches away from the advantage of sterilizing a filter using a separate method from that used to sterilize other components (col. 16, lines 1-16, unit sterilized entirely).

14. Examiner also notes that Goldhaber et al. (US Patent 5,269,946) discloses the limitations of:

a primary bag and secondary bag (col. 4, lines 64-68, Figs. 1-4, primary bag 16 and container / transfer bag 34);

a filter (col. 5, lines 30-37, Figs. 1-4, separation device 40); and

hermetically cutting and sealing tubing components connecting bags (col. 8, lines 34-46, especially lines 39-44, Fig. 6, devices 66a-66d). However, Goldhaber lacks the critical step of cutting a second tube attached to a filter as claimed [claims 3 and 4], since separation device 40 is disclosed as being initially attached to a bag (cols. 7-8, lines 62-4, especially lines 1-4, Fig. 6, subassembly 64 comprising separation device 40 connected to transfer bag 34).

15. Lastly, Corbin et al. (US Patent Application Publication No. 2003/0146170) discloses the limitations of:

a primary bag and a plurality of secondary bags (§ [0065], Fig. 3, blood collection bag 5 and blood product satellite bags 61-64);

a filter (§ [0065], Fig. 3, leukocyte removal filter 26); and

hermetically cutting and sealing tubing components connecting bags (§ [0033], splicing tubes using sterile docking methods). Corbin further discloses filtering blood through a bag and filter set not connected to other bags (§ [0029], [0032]). However, Corbin lacks the critical step of cutting a second tube attached to a filter as claimed [claims 3 and 4], since this filter is disclosed as already attached to a bag.

16. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- ❖ Wisdom; Leonard A. US 4596657
- ❖ Stewart; Mary A. US 4997577
- ❖ Page; Roger E. et al. US 5601730
- ❖ Mari; Giorgio et al. US 20060086666
- ❖ Carmen; Raleigh A. et al. US 5089146
- ❖ Goudaliez; Francis et al. US 7048709
- ❖ Verri, Paolo et al. US 20050082218
- ❖ Verpoort, Thierry et al. US 20030150793

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is (571)272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

//Leslie R. Deak//
Primary Examiner, Art Unit 3761
11 September 2008